Part 4 - Session Papers for the EPA 22nd Annual National Conference on Managing Environmental Quality Systems

April 14-17, 2003 New Orleans, Louisiana

ENVIRONMENTAL STATISTICS ADVANCEMENTS

Indexing Environmental Quality Indicators: A Multiple Criteria Decision-making Approach to the session Environmental Statistics Advancements * - Ranjan Maitra, University of Maryland Baltimore County

Using the Web for Multi-media Analysis * - Cynthia Curtis, U.S. EPA

NELAC

Lessons Learned from Basic Assessor Training - Marlene Moore, Advanced Systems, Inc.

How ISO 17025 and PBMS Are Part of the NELAC 2002 Quality Systems Chapter - Robert P. Di Rienzo, VP of DataChem Laboratories, Inc.

A New Look for NELAC * - Silky Labie, Florida Department of Environmental Protection

ENVIRONMENTAL DECISION MAKING

Development of Measurement Performance Criteria - Dan Michael, Neptune and Company

STATISTICAL MODELING OF AIR QUALITY

Network Design for Ozone Monitoring * - D. Holland, U.S. EPA

Spatial Variability of Pollution Concentrations on a National Scale * - T. Fitz-Simons, U.S. EPA

Impact of April 2001 Asian Dust Event on Particulate Matter Concentrations in the United States * - D. Mintz, U.S. EPA

QUALITY ASSESSMENT AND IMPLEMENTATION PRACTICES

Development of an ETD Preaudit Technical Checklist for Audits of EPA Research Studies - Thomas J. Hughes, U.S. EPA

Quality Assurance Audits - Positive Outcomes * - Joseph LiVolsi, U.S. EPA

Planning Environmental Data Collection Programs; Perspectives from Nigeria * - Ibrahim Salau, ERML

INTERNAL AUDIT OF ELECTRONIC DATA SYSTEMS

Developing and Implementing Universal Standards for 'Quality Electronic Records Practices' and the State-Of-The-Art of Electronic Lab Notebooks * - Dr. Richard S. Lysakowski, Jr., the Collaborative Electronic Notebook Systems Association and the Global Electronic Records Association

WORKSHOPS

Measurable Product Features for Information * - Jeffrey Worthington, U.S. EPA

Red Bead Experiment * - Jeffrey Worthington, U.S. EPA

Conducting Internal QMS Audits - Gary Johnson, U.S. EPA

Environmental Decisions Using Data Expressed with the Measurement Uncertainty - Marlene Moore, Advanced Systems, Inc.

How to Incorporate Information Quality Considerations into Your Existing Quality Management Plan * - Jeffrey Worthington, U.S. EPA

* **Abstract Only**

Indexing Environmental Quality Indicators: A Multiple Criteria Decision-making Approach

Ranjan Maitra, Department of Mathematics and Statistics,
University of Maryland Baltimore County, Baltimore, MD, USA.

Environmental data quality indicators come from several sources and often represent different aspects of the environment. Combining these indicators to come up with an overall index is important for planning and policy and also to understand different environmental impact. We present here a data-driven multiple criteria decision-making (MCDM) approach. The methodology is implemented on data on toxic releases in the 50 U. S. states as well as on air, water and land quality in both the US and 106 countries of the world. Further analysis is done on homogeneous clusters of the U. S. air, water and land data.

(This work is joint with N. Phillip Ross of the United States Environmental Protection Agency, Jim Lee and Suzannah Herczek of American University, and Bimal Sinha of UMBC.)

Using the Web for Multi-media Analysis

Cynthia Curtis US EPA Region 5

U.S. EPA Region 5 has developed a pilot intranet web site designed for the display of analytical data and to provide information to enable reporting on the state of the environment. The system is closely aligned with the National State of Environment reporting structure The concept and initial design of this system was presented at the last U.S.EPA statistics conference in 2001 . Updates to the website have greatly enhanced data transparency and set the stage for sound statistical analysis of the state of the environment.

We will review both the successes and challenges experienced during the development of this system. Success stories will include collaboration with other U.S. EPA Regions and tapping into each others expertise to develop more sophisticated analyses. We will also discuss current cultural and technical obstacles to expand and enhance our online multi-media analysis system.

Lessons learned from Basic Assessor Training

Marlene Moore, Advanced Systems, Inc.

The presentation includes information gathered from the participants and lessons learned from presenting the Basic Assessor Training course as required by the NELAC standard. Training has been offered for over one year in accordance with the NELAC Chapter 3 Appendix A standard. The NELAC community adopted this standard for the Basic Assessor Training course in July 2001. As part of the training, an exam is given and a passing scope of 70% or higher is required to receive a certification of completion. The presentation reports on the benefits identified by the participants in taking the training. Comments to enhance the course curriculum and suggestions for possible changes to the NELAC standard will also be discussed.

The requirements for Basic Assessor training are found in Chapter 3 Appendix A of the 2001 NELAC standard. The course contents, purpose, logistics and examination requirements are defined in this standard. The purpose of the course is to:

- Instruct assessors on the basic elements of performing NELAC assessments by focusing on evaluating laboratory quality systems and the competency of the laboratory to perform the test methods on the scope of accreditation.
- Provide an overview of the NELAC Standards and the NELAP laboratory accreditation process.
- Promote uniformity of laboratory assessments performed to obtain NELAP accreditation.
- Facilitate information exchange among assessors.

The course materials cover the following elements that are detailed in the NELAC Standard, Chapter 3 Appendix A.

- ✓ Historical Perspective On National Accreditation
- ✓ Fundamentals Of NELAC And NELAP
- ✓ Qualifications And Training Requirements For Assessors
- ✓ Accreditation Of Laboratories
- ✓ Proficiency Testing
- ✓ Ethical Conduct Standards For Assessors
- ✓ Quality Systems
- ✓ NELAC Quality System Checklist
- ✓ Interviewing Techniques For Assessors
- ✓ NELAC Laboratory Assessments
- ✓ Pre-Assessment Activities
- ✓ On-Site Assessment Components
- ✓ Post On-Site Assessment Activities
- ✓ Handling Assessment Challenges

- ✓ Course Summary And Conclusions
- ✓ Final Examination

The first course was offered in March/April 2000. The original course was a five-day class presented in Maryland and California and included the initial accrediting authority assessors. The materials from that class are found on the NELAC web site. The information and input from the first course was used to develop a standard for the course which is presented in NELAC 2001 standard, Chapter 3, Appendix A.

Anyone can develop a basic assessor training class that meets the standard. This presentation summarizes the lessons learned from a course prepared and presented by Advanced Systems, Inc. The course contents are delivered in a traditional classroom setting. The course lasts for three days and provides examples of data review, conducting interviews and writing deficiencies. The timeframe for the course was reduced from 5 days to 3 days by not spending time in the classroom reading the standard. Prior to attending the class, each student must read and study the NELAC standard with additional studying required in the evening of the first two days of class. The course is prepared for 2.5 days of classroom instruction with group exercises and 0.5 day in the classroom for testing and review of the final examination.

The current version of this course has been updated two times, since its first offering in October 2001. This is due to the changes to the standard, from 2000 to the 2001. Every year the course is revised for the new standard contents and improvements provided by students. The course provides opportunity for ample interaction between instructors and participants and includes group exercises designed to be completed by teams of participants.

Class sizes have ranged from 4 to 30 students. The classroom size works best around 15 students. When more than 15 students are signed up at least 30 days before the class, a second instructor is required. The second instructor is needed in order to assist with helping students during classroom exercises and providing classroom instruction.

The larger classes find a more diverse audience with a variety of learning levels. The results recorded on the evaluations of these larger offerings indicate the classroom instruction was too slow and also indicates the instruction was too fast. It really underscores the need to have students with similar experience levels in order to ensure the most information is transmitted to the students during the time spent in class. In addition when the students are more diverse in experience it results in those with little to no experience not participating and those with more experience sharing additional information, which although useful, does not train the more experienced students in additional auditing tips and techniques. Past experience in the laboratory as well as exposure to the assessment process may need to be specified as pre requisites to the training course. Some of the past experience should include managing of personnel, projects or laboratory operations.

The ISO/IEC 17025 and ISO/IEC Guide 25 are management system standards. These standards are part of the NELAC standard Chapter 5. This means that they include technical aspects such as method and analyst performance, but also include the evaluation of the effectiveness of the management system. This requires the assessor to have an understanding of the management of a laboratory. Many technical personnel at the bench do not have the sufficient experience in management to understand some of the concepts related to personnel training; supervision and other management concepts presented in the ISO/IEC standards. Personnel attending the class with less than a few years of bench experience do not recognize some of the management attributes of the standard that are required for the full operations of a testing laboratory.

The standard for the course does not currently require a minimum set of qualifications and experience for classroom participation. Some students have noted in the evaluation forms that prerequisites should be required. Suggestions include participation in or observed of at least one NELAP assessment, have supervisory or other experience in managing data, projects or personnel and having working knowledge and experience of the laboratory test methods. It is noted that analysts with no audit experience or little to no experience in managing do not fair as well as in the examination and in the classroom exercises.

Participants include laboratory personnel from the private and public sectors, assessors and data users. Accrediting authorities approve the training for their assessors and it is the responsibility of accrediting authorities to qualify and approve their assessors. Therefore this training course is not approved by NELAC or NELAP and must be recognized by the accrediting authority in order to satisfy the requirement of a basic assessor training class. In other words, taking and passing the class is only one of the requirements to be a NELAP assessor.

Participants are offered an opportunity to take a written examination that quantitatively measures their knowledge of the NELAC standards and the course contents. Students taking the examination must obtain a score of 70% or more to be classified as successfully completing the course.   No scores are given out and a system for reexamination is available if the student does not obtain a 70% or better on the exam. Certification of completion indicates that a student has passed. A student may elect to attend the class and not take the final examination, in which case the person receives a certificate of attendance.

The test has proven beneficial, and many have commented that without the test, they would not have studied the standard as in depth as if there was no test to prepare for before and during the class. The test does the job in getting the students to read the standard.

The test is given in English and some are having trouble with the questions since English is not their first language. Poor testing does not always mean that the person does not understand the standard. The test forces people to study the standard and become familiar with it. It also teaches everyone to be able to locate information quickly and obtain an understanding of the intent of the standard. It also brings out sections of the standards that are not clearly worded. As a result assessors must learn how to interpret and handle these situations.

Many assessors do not attend the NELAC meetings where the standards are written and discussed. Therefore the interpretation of the intent becomes unknown or it's not clear if the standard wording is not concise. In more severe cases, this is where the majority of state differences are seen. A few examples recently presented to committee chairs were, the definition of deficiency and whether an assessor must document all deficiencies or only those that are a "real problem". When does an assessor know what is a real problem or just not meeting the standard? These discussions help both new and experienced assessors as well as those from the laboratory to understand that they must document conformance to the standard and where some observations may not fit exactly into the requirements these should be documented in the report. Only those items that are clearly not meeting the intent of the standard must be cited as deficiencies.

In the class the assessor learns how difficult it is for a laboratory to understand and interpret the standard for implementation as well as the laboratory staff attending the class learn how difficult it is for the assessor to determine conformance. Both the laboratory and assessor must be thoroughly knowledgeable on the intent, science and practical implementation constraints of the standard. The sharing of information during the classroom discussions becomes some of the most valuable to laboratory personnel, assessors and the instructors. During these classroom discussions, the variety of interpretations to the standards is uncovered and the participants are taught to handle these multiple interpretations by dealing with a discussion and acceptance of sound science as conformance to the intent of the standard. The demonstration of conformance to the NELAC standard must ensure that the data is of known and document quality. It does not mean that it is performed and implemented only one way. The NELAC standard allows flexibility in the implementation. It is not a prescriptive standard and therefore, must be assessed by an assessor who recognizes that the laboratory management has defined the practices, procedures and performance standards to provide data of a known and documented quality.

In summary, what we have learned is:

- Classroom size is best at 15 to 20 students
- Everyone reads the standard in order to obtain a passing grade on the exam
- Everyone gets nervous about an exam
- Systems assessments are a new concept and require experience in managing self, test area, facility or laboratory.
- Laboratory personnel taking the class learn its not easy being an assessor
- Assessors taking the class learn that its not easy be questioned about information found in your laboratory.

References:

Guidelines for training Courses for Assessors Used by Laboratory Accreditation Schemes, ILAC-G3; 1994

National Environmental Laboratory Accreditation Conference (NELAC) Standard, approved May 2001 and July 2002, US EPA

How ISO 17025 and PBMS are part of the NELAC 2002 Quality Systems Chapter

Robert P. Di Rienzo

The focus of this paper will be on the changes to NELAC Chapter 5 "Quality Systems" that were adopted in July 2002. Proposed changes and clarifications to this adopted standard will also be presented. The proposed changes will be voted on in San Diego, CA at NELAC IX in June 2003.

Summary

- ➢ NELAC 2002 Chapter 5
- ISO 17025
- Proposed Changes for 2003

- ➢ Performance Based Measurement Systems
- NELAC 2002 Chapter 5
- Proposed Changes for 2003

ISO/IEC 17025

➢ *"General Requirements for the Competence of Calibration and Testing Laboratories*"

➢An International Quality Standard

➢ISO 17025 is worldwide and will ensure consistency in the quality of accredited laboratories

➢*ISO 17025 provides guidance to owners and operators of laboratories on both quality management and technical requirements for the proper operation of a testing laboratory.*

NELAC 2002 Chapter 5

➢Changes to Format of 2001 Chapter 5

- Follows 17025 Format

- Clearly Identifies Management Requirements and Technical Requirements

NELAC 2001 Chapter 5

- In the 2001 format all sections seemed to have both management and technical requirements.

- Management Requirements
  - 5.4 Organization and Management
  - 5.5 Quality System
  - 5.12 Records
  - 5.14 Subcontracting Analytical Samples
  - 5.15 Outside Support Services and Supplies
- Technical Requirements
  - 5.6 Personnel
  - 5.7 Physical Facilities…
  - 5.8 Equipment and Reference Material
  - 5.9 Measurement Traceability/…
  - 5.10 Test Methods and SOPs
  - 5.11 Sample Handling….
  - 5.13 Laboratory Report Format and Contents

NELAC 2002 Chapter 5

- 5.4 Management Requirements

- 5.5 Technical Requirements

- All NELAC 2001 Chapter 5 requirements are addressed in NELAC 2002 Chapter 5

- If ISO 17025 standard language did not adequately address the NELAC 2001 Chapter 5 requirements, than it was added to the appropriate section

- A cross reference table was added as Appendix F

NELAC 2002 Chapter 5
New ISO 17025 Management Requirements

- 5.4.1
  - Conflicts of Interest
- 5.4.3
  - Document Control
  - Document Approval and Issue

- Document Changes

➢5.4.4
- Review of Requests, Tenders and Contracts

➢5.4.6
- Purchasing

➢5.4.7
- Service to Client

➢5.4.9
- Control of nonconforming work

➢5.4.10
- Corrective Actions

➢5.4.11
- Preventative Actions

➢5.4.12
- Control of Records

New ISO 17025 Technical Requirements

➢5.5.2
- Personnel

➢5.5.4
- Selection of Methods
- Laboratory Developed Methods
- Non-Standard Methods
- Validation of Methods
- Estimation of Uncertainty

➢5.5.10
- Test Reports - Results of Sampling
- Test Reports - Opinions and Interpretations

NELAC 2002 Chapter 5
Proposed Changes for 2003

➢ Calibration Laboratories – Removal of reference to and activities of Calibration Laboratories. AAs do not accredit Calibration Laboratories.

➢ Changes to Chapter 5 include:
- Changes from comments received
- Changes to Chapter 1, glossary

- Appendix D2 Toxicity Testing and D4 Radiochemical Testing
- PBMS changes (Chapter 5, Appendix C and D)

Performance Based Measurement Systems

➢NELAC VIi Las Vegas, NV
- Straw-model presented by ELAB
- Passed to Quality Systems Committee

➢NELAC VII Salt Lake City, UT
- Subcommittee formed – Integration of PBMS into Chapter 5

➢NELAC VIIi Arlington, VA
- Subcommittee Report – Not ready for voting at NELAC VIII

➢NELAC VIII Tampa Bay, FL
- Short Presentation by PBMS Subcommittee

➢NELAC VIIIi Sante Fe, NM
- Proposal of changes to Chapter 5 and appendices
- Meeting in Edison, NJ on proposed changes.

➢NELAC IX San Diego, CA
- Voting on changes to 2002 Standard

The NELAC 2002 Chapter 5 addresses PBMS under both management and technical requirements

- ➢ Management Requirements
- 5.4.4 Review of Requests, Tenders and Contracts
- ➢ Technical Requirements
- 5.5.4 Environmental Test Methods and Method Validation

PBMS Management Requirements
5.4.4 Review of Requests, Tenders and Contracts

- The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts…..

- the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.5.4.2);

- Records of reviews, including any significant changes, shall be maintained….

- the appropriate environmental test method is selected and capable of meeting the clients' requirements (see 5.5.4.2).

PBMS Technical Requirements
5.5.4 Environmental Test Methods and Method Validation

- The laboratory shall use methods for environmental testing, including methods for sampling, which meet the needs of the client and which are appropriate for the environmental tests it undertakes.

- The introduction of environmental test methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.

- When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the environmental test.

- Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

- The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use.

    - The range and accuracy of the values obtainable from validated methods (e. g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the clients' needs.

NELAC 2002 Chapter 5
PBMS Proposed Changes for 2003

➢Sources of Methods

- When the client does not specify the method to be used or where methods are employed that are not required, as in the Performance Based Measurement System approach, the methods shall be fully documented and validated (see 5.5.4.2.2, 5.5.4.5, and Appendix C),

➢Validation of Methods

- The minimum requirements shall be the initial test method evaluation requirements given in Appendix C.3 of this chapter.

C.3 INITIAL TEST METHOD EVALUATION

For Chemistry, Radiochemistry, Air, and Asbestos Microscopy testing, initial test method evaluation requirements consist of the requirements specified in C.3.2 though C.3.4 below. For Toxicity testing, and Microbiology testing, the initial test method evaluation requirements are contained at Appendix D.2. and D.3., respectively.

C.3.1. Limit of Detection (LOD)

The laboratory shall confirm the LOD for the method for each target analyte of concern in the relevant sample matrices.

All sample-processing steps of the analytical method shall be included in the determination of the LOD.

The validity of the LOD shall be confirmed by qualitative identification of the analyte(s) in a QC sample in each relevant matrix containing the analyte at no more than 2-3X the LOD for single analyte tests and 1-4X the LOD for multiple analyte tests. This verification must be performed on every instrument that is to be used for analysis of samples and reporting of data.

A LOD study is not required for any component for which spiking solutions or quality control samples are not available such as temperature, or, when test results are not to be reported to the LOD (versus the limit of quantitation or working range of instrument calibration), according to Appendices D.1.2, D.4.5, D.5.4, and D.6.6. Where an LOD study is not determined, the laboratory may not report a value below the Limit of Quantitation.

C.3.2. Limit of Quantitation (LOQ)

The laboratory shall confirm the (LOQ) for each analyte of concern according to a defined, documented procedure, such as required in Appendix D.1.2.g.

The LOQ study is not required for any component or property for which spiking solutions or quality control samples are not commercially available or otherwise inappropriate (e.g., pH).

The validity of the LOQ shall be confirmed by successful analysis of a QC sample containing the analytes of concern in each quality system matrix at or near the claimed LOQ. A successful analysis is one where the recovery of each analyte is within the established test method acceptance criteria or client data quality objectives for accuracy (bias). This single analysis is not required if the bias and precision of the measurement system is evaluated at the LOQ.

C.3.3. Evaluation of Precision and Bias

The laboratory shall evaluate the Precision and Bias of a Standard Method for each analyte of concern for each quality system matrix according to the single-concentration four-replicate recovery study procedures in Appendix C.1 above (or alternate procedure documented in the quality manual when the analyte cannot be spiked into the sample matrix and QC samples are not commercially available).

For Laboratory-developed test methods or non-standard test methods as defined at 5.5.4.3 and 5.5.4.4. that were not in use by the laboratory before July 2003, the laboratory must have a documented procedure to evaluate precision and bias. The laboratory must also compare results of the precision and bias measurements with criteria established by the client, by criteria given in the reference method or criteria established by the laboratory.

Precision and bias measurements must evaluate the method across the analytical calibration range of the method. The laboratory must also evaluate precision and bias in the relevant quality system matrices and must process the samples through the entire measurement system for each analyte of interest.

Examples of a systematic approach to evaluate precision and bias could be the following:

Analyze QC samples in triplicate containing the analytes of concern at or near the limit of quantitation, at the upper-range of the calibration (upper 20%) and at a mid-range concentration. Process these samples on different days as three sets of samples through the entire measurement system for each analyte of interest. Each day one QC sample at each concentration is analyzed. A separate method blank shall be subjected to the analytical method along with the QC samples on each of the three days. (Note that the three samples at the LOQ concentration can demonstrate sensitivity as well.) For each analyte, calculate the mean recovery for each day, for each level over days, and for all nine samples. Calculate the relative standard deviation for each of the separate means obtained. Compare the standard deviations for the different days and the standard deviations for the different concentrations. If the different standard deviations are all statistically insignificant (e.g., F-test), then compare the overall mean and standard deviation with the established criteria from above.

A validation protocol such as the Tier I, Tier II, and Tier III requirements in US EPA Office of Water's Alternate Test Procedure (ATP) approval process.

C.3.4. Evaluation of Selectivity

The laboratory shall evaluate selectivity by following the checks established within the method, which may include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.

Changes proposed to Chapter 1 Glossary

- Limit of Detection (LOD): an experimentally determined lowest concentration or amount of a target analyte that can be measured and reported with confidence that the analyte is not a false positive. (See also Method Detection Limit)

- Limit of Quantitation (LOQ): levels, concentrations, or quantities of targeted analytes that can be reported at a specified degree of confidence. The lower and upper quantitation limits are defined by the lowest and highest concentrations used for calibration.

A New Look for NELAC

Silky Labie, Florida Department of Environmental Protection

The times they are a changin' and NELAC is changing, too. This presentation will provide an overview of the changes that will be made at the end of the NELAC 9 to be held in San Diego in June 2003. Also included will be updated information on the status of various transitions to the new structure.

Development of Measurement Performance Criteria in Support of Environmental Decision Making

Daniel Michael, Neptune and Company, Inc.

The QA Project Plan (QA/G-5) Section 2.1.7, calls for the specification of "Quality Objectives and Criteria for Measurement Data". Specifications are required at two levels: the level of the decision (or study question), and the level of the measurements used to support the decision. The Data Quality Objectives (DQO) process addresses this first level, and includes a design optimization step, where specifications at the second level can begin to emerge. Sampling and data quality indicator guidance QA/G-5S, QA/G-5i) add considerable detail related to quality planning and design, however none of the available guidance documents fully addresses the process of developing measurement performance criteria. This paper is intended to begin to tie together information from these various sources and more directly address what occurs within Step 7 of the DQO process and how it can lead to the development of measurement performance criteria.

A critical input to conducting the analyses in Step 7 is a relevant estimate of total study variance, and an understanding of the relative contribution of the major components of this variance term. Using this information we can explicitly look at trade-offs between alternative measurement methods as part of the design optimization process. After selecting a design, criteria can be developed that are directly linked to the assumed variance and sensitivity in the design. The nested nature of these criteria, and the logic flow associated with consideration of these issues will be discussed.

Introduction

QA Project Plans, work plans, and sampling and analysis plans, are routinely generated to support new data collection efforts. EPA guidance (EPA 2000a, 2002b) and associated consensus standards (ANSI/ASQC, 1994) are used to guide the planning process, selection of a sampling design and development of these planning documents. A closer examination of planning documents based on these guides reveals that the current approaches used to develop specifications within these documents rely heavily on the status-quo, and rarely are specifications for the measurement side of the problem based on the outcome of a design optimization process (personal observation). Several recent papers have stressed the need to carefully consider the myriad of details associated with a data collection effort (Maney, 2002, Lesnik et al 2002). For example, while attention is commonly paid to ensuring that analytical methods with a detection limit below a threshold value are selected, measurement quality objectives (MQOs) are generally not explicitly linked to design requirements. Instead, criteria for measurement precision and bias simply reflect historically used specifications (e.g., levels specified in a previous QAPP) and these specifications may have little relevance to the new study.

The intent of this document is to provide an introduction to a new QS guidance document that is being written to assist those designing sampling and analysis plans in developing a stronger basis for the MQOs. The central theme of this guidance is to simultaneously evaluate the measurement side of the design problem during the design optimization step in parallel to evaluating different sampling designs. In this way, measurement quality objectives established during planning, and documented in a QA Project Plan are linked to the ultimate goal of the study: to control uncertainty in the end use (e.g., decision making) of the data.

At first glance, it may appear that by asking that measurement error be explicitly considered during the development of the design (as part of the quantitative analysis of design alternatives), the intent is to reduce this source of error. In fact, this may not be the case at all. If you consider that it has become more evident over time that spatial and temporal heterogeneity, and associated sampling error, are frequently the dominant term in the total study error equation, then it follows that the performance of the design is more dependent on controlling sampling error then controlling measurement error. This understanding has opened the door to considering a more extensive use of rapid characterization or field measurement methods as part of the toolbox used to come up with a design. This is a key element of the "triad approach" that has been developed by Superfund's Technology Innovation Office – which combines systematic planning and the use of field methods with an adaptive or dynamic work plan, as an effective means of generating effective data in support of hazardous waste clean-up decisions (Crumbling et al.2001).

Getting Ready to Design a Data Collection Effort

Effective design optimization starts with a review of planning outputs. EPA's guidance "Choosing a Sampling Design for Environmental Data Collection" (EPA 2002) emphasizes the need for clearly stated objectives, including quantitative acceptance or performance criteria. In addition, it is important to have a clear understanding of practical constraints on budget, schedule, special equipment, personnel etc.

The development of a design for collection of environmental data can range in scope from a detailed, statistically based approach, to a more qualitative approach based on professional judgment. So too, can the process of establishing measurement performance criteria, as part of this design. To accommodate this range of potential studies, a graded approach to data collection design makes sense. When practical and deemed beneficial for a given project, the effort to develop a well conceived statistical design can provide a rigorous basis for selection of MQOs. However, for some environmental studies, it may become clear that a quantitative, statistical approach is either not warranted, or not practical; and a design based on professional judgment is either preferential, or simply must be accepted.

For projects that warrant a more quantitative design effort, we assume that systematic planning (e.g., DQO's or PAC) has resulted in the development of the full set of specifications needed to support a quantitative design (or the planning team is willing to stop and complete the systematic planning process to develop such objectives). The outputs of key importance to developing a quantitative sampling and analysis design include:

- the identification of the key variables or inputs of interest (and if possible the identification of the one or two variables that will drive the design),

- boundaries of the study (including how sampling units are defined and the scale of the decision),
- decision rule, and
- any decision performance goals (and associated statistical formulation of the hypothesis of interest).

Electing to develop a design based primarily on professional judgment does not lessen the importance (or utility) of systematic planning. Many of the same outputs used in statistical designs will also be key to developing an effective design based on professional judgment. For example, the objectives (study questions or decision) still need to be clearly stated, the measurements required to support these objectives identified, and the boundaries that define the spatial area and/or timeframe to be represented by measurements documented. It will also be important to consider, and document, how the data to be produced will be summarized and used to support the objectives. If the intent is to compare results to established thresholds of some sort, this information will be needed to ensure that measurement methods with adequate sensitivity are selected for the study.

The main difference between the judgment-based and statistically based design lies in the explicit (mathematical) consideration of the magnitude of error that can be tolerated. Statistically based designs create a mathematical model that facilitates the calculation of design performance based on a range of inputs (e.g., sample size, sample allocation, and different analytical measurements that vary in terms of precision, sensitivity and bias). Judgment-based designs base the determination of how many samples to take, where and when to take them, and the selection of the analytical method(s) to be used and measurement quality objectives (MQOs) on experience. In both cases, it is highly preferential to introduce randomness into the placement of samples to ensure that summary statistics such as the mean represent the population of interest; unless the design is intentionally biased (in which case randomization within the specific area of interest is still desirable).

The Design Effort

QA-G-5S (EPA 2002) describes two generic approaches that can be considered: an episodic design intended to achieve the study objectives with one or more discrete episodes of sampling, or an adaptive design that envisions multiple somewhat continuous phases of sampling and analysis under a single *dynamic work plan***.** The adaptive approach can be envisioned as a punctuated sequential design that relies on the availability of a rapid field analytical method that can be used to generate data that are used "real-time" by a dedicated project team (who is available in the field) to guide the design without multiple mobilization efforts.

In situations where rapid analytical methods are not available or not deemed adequate (e.g., sensitivity may not be good enough), or in situations where a more traditional episodic design is required (e.g., due to funding constraints), the importance of careful design (determination of the type and number of samples, and development of MQOs) is heightened. In these cases, the quality and relevance of historical data upon which the design is based is a key issue, since there will be no opportunity to adapt to observations or measurements made during the study.

Evaluating Existing Information in Support of the Design Evaluation Process

Existing data (or new data collected during a preliminary episode of data collection) typically provides the strongest basis for developing the design for new data collection. At a minimum, these data are used for developing a site conceptual model, and for generating quantitative values to support the evaluation of design alternatives. A conceptual model that organizes existing information about an environmental problem is useful for most studies, not just for hazardous waste sites. The conceptual model should include at least the physical dimensions of the problem (sources, media, pathways for fate and transport in the environment), and in some cases will include more information on exposure pathways and receptors. The values required to support the design effort include the range of concentrations observed, and an estimate of the total study variance as well as estimates of major components of total study variance.

A good place to start to determine if there is a good statistical basis for a design is the organization and evaluation of existing data to see what is known about the distribution and variability of the variable(s) of interest. The analysis of components of study variance typically involves obtaining field and corresponding QA/QC data in an electronic form, or entering data from tables into a computer for analysis. Assuming measurement data are available that at least in part represent the area of interest, the available data set can be scrutinized or mined to determine the overall variability, variability associated with the analytical measurement process that was used [e.g., through an analysis of the mean variance of field duplicates (collocated or split samples) and/or laboratory duplicates].

In the ideal case, historical data are mined to obtain ***relevant*** estimates of variance for the variable(s) expected to drive the design. By ***relevant*** we mean that the estimate is derived from data from the area (and/or time period) of interest, using methods for sample collection (to ensure sample support is comparable) and analysis (including sample preparation techniques) that are at least similar to that under consideration for the new study. If such data are rare, or non-existent, and time or other constraints prohibit an adaptive or phased approach, the ability to optimize a statistical design may be severely limited.

It is possible to come up with the sample size required by just having an estimate of total study variance (assuming the same measurement methods employed previously will be used again). However, if there is a desire to consider other measurement methods, or to have a quantitative basis for MQOs, the relative magnitude of within-unit and between-unit components to the total variance need to be evaluated. Typically, data collected from a historical study will be useful for estimating a total study variance, and for breaking out what portion of the total can be ascribed to within-unit (or at least measurement) variance by looking at the mean variance of duplicate pairs. Through subtraction one can estimate that portion of the total variance that is due to the heterogeneity of the variable of interest in the environment (such as the concentration of some heavy metal in soil).

A number of the major components of total study variance can be estimated from commonly collected QA/QC and field samples. For guidance on estimating components of variance from the available field and laboratory replicates, please see the Data Quality Indicators Guidance: QA/G-5i, Section 4 (EPA 2003, in press).

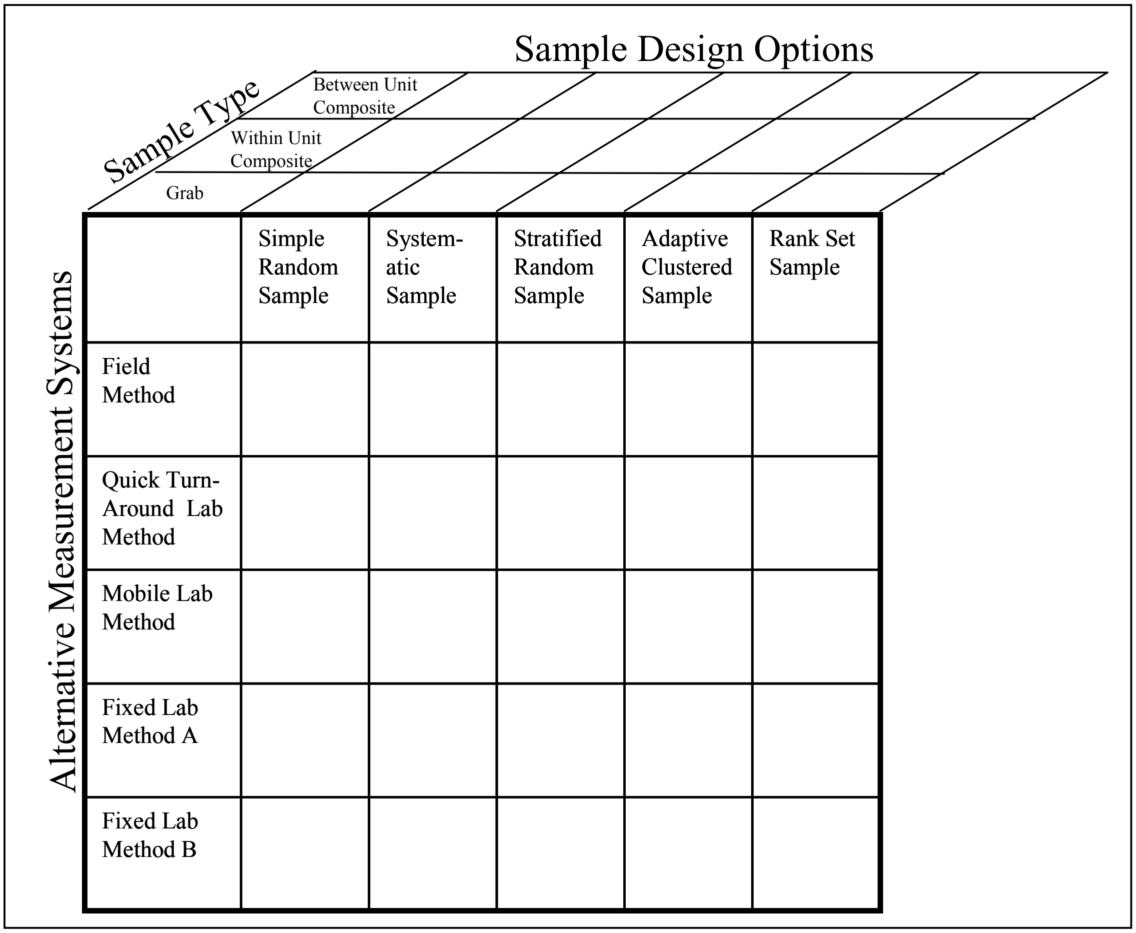
Selecting The Sample Allocation Strategy and Measurement Method

EPA's Guidance on Choosing a Sampling Design for Environmental Data Collection (EPA 2002) provides a number of alternatives that can be considered, along with equations to determine the number of samples required to achieve desired limits on decision errors. Assuming data are sufficient to understand and generate estimates of the major components of total study variance, then the planning team can discuss design alternatives and begin to narrow the field of potential designs to a more discrete list. Figure 1 provides a matrix of possible design alternatives from which the narrowing process can begin. Each of the components of this matrix is discussed at some level in QA/G-5S, with the possible exception of using composite samples to control within-unit variance, as opposed to using composites to obtain an estimate of the mean of the population of interest.

The use of this matrix emphasizes the concept that more than one sample design, combined with more than one measurement method, should be considered with or without use of small or large-scale composite sampling. Specific MQOs emerge from the simultaneous evaluation of the expected performance of the sampling alternatives coupled with different measurement methods, and coupled with considering whether composite sampling can help reduce the spatial variability. Having selected the preferred alternative (usually the lowest cost combination of design variables that achieves the systematic planning outputs), the assumed variance contributions are also selected, and can be used to set a meaningful MQO in the QA Project Plan.

Composite sampling is emphasized in the matrix for two reasons. First, if the objective of the study is to generate an estimate of the population (or sub population) mean, then composite sampling at various scales (e.g., population, subpopulation or within sampling unit) might be worth considering. Second, if the spatial variability can be controlled using compositing, the importance of measurement variability may increase, since it may become a significant contributor to the total study variance. However, if there is a strong political or technical reason why compositing is not acceptable, then one dimension of the matrix can be removed from consideration. Technical reasons limiting the use of compositing include loss of volatile constituents during the homogenization of aliquots, the inability to detect concentrations of interest within the homogenized sample, or a strong desire to understand spatial variability (between sampling units) within the population. Even if the latter is the objective, it may be acceptable/beneficial to consider compositing within-sampling units to reduce small-scale variability (effectively increasing the sample support). Given the fact that most environmental samples contain a good deal more material than will be subjected to the detector in the analytical instrument – all samples can be considered a form of composites. It is routine practice to homogenize material as part of the sample preparation effort – so the only real change is that multiple grabs might be taken prior to homogenization, thereby physically averaging the media over a larger area prior to analysis.

Figure 1. Matrix of Possible Design Options



References

1) Crumbling, D., C. Groenjes, B. Lesnik, K Lynch, J. Shockley, J. VanEe, R. Howe, L. Keith, and J. McKenna. 2001. *Managing Uncertainty in Environmental Decisions*. Environmental Science and Technology, Volume 35, No 19.
2) USEPA, 2002a. *Guidance on Choosing a Sampling Design for Environmental Data Collection for Use in Developing a Quality Assurance Project Plan*. EPA QA/G-5S.
3) USEPA 2002b. *Guidance on Developing Quality Assurance Project Plans*. EPA QA/G-5.
4) USEPA, 2003. *Guidance on Data Quality Indicators*, EPA QA/G-5i. In press.
5) Maney, J.P., 2002, *Optimizing Data Collection Design.* Environmental Science and Technology, October, 2002.
6) ANSI/ASQC E4 (1994) *Specifications and Guidelines for Environmental Data Collection and Environmental Technology Program*. American Society for Quality. Milwaukee, WI.
7) Lesnik, B and D. Crumbling, 2001 *Guidelines for Preparing SAPs Using Systematic Planning and PBMS.* Originally published by Environmental Testing & Analysis, Jan/Feb 2001, available at clu-in.org

Network Design for Ozone Monitoring

David M. Holland, U. S. EPA, Office of Research and Development; Arin Chaudhuri, Montserrat Fuentes, North Carolina State University, Department of Statistics

The potential effects of air pollution on human health have received much attention in recent years. In the U.S. and other countries, there are extensive large-scale monitoring networks designed to collect data to inform the public of exposure risks from air pollution. A major criterion for modifying an existing network is the suitability of spatial predictions based on site measurements at non-monitored areas. These spatial predictions can be used to develop better pollution control strategies for protecting human health. To accomplish this, it is important to ask what monitoring coverage is required to allow optimal, in some quantitative sense, predictions of the spatial field. We consider new approaches for network designs based on entropy criteria and modeling the underlying nonstationary covariance structure of atmospherically driven pollutant processes. In general, entropy is defined as maximizing "information" expected about potential non-monitored locations. Sites with observations near air quality standards are given higher priority in a combined entropy-air standard design criterion. Eight-hour daily maximum ozone values observed at 513 National Air Monitoring sites are used to demonstrate several network designs.

Spatial Variability of pollution Concentrations on a National Scale

Terence FitzSimons, U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards

Spatial variability is a very important quality of air pollutants for many areas of agency policy. Obviously, monitoring regulations depend heavily upon knowledge of spatial variability. Control strategies also depend heavily on this knowledge (will a local or regional program be more effective?) As does action day programs and public information programs.

Traditionally, spatial variation has been depicted by isopleth maps, concentration maps, box plots of various sites. Does this really give us useful knowledge about spatial variation? This paper explores a new way to explore spatial variability of a large scale and also presents an extension of this method in an attempt to characterize spatial variability in a useful way. The new methodology is presented along with its application using data from several criteria pollutants.

Impact of April 2001 Asian Dust Event on Particulate Matter Concentrations in the United States

David Mintz, U.S. Environmental Protection Agency; Jim Szykman, U.S. Environmental Protection Agency; Jack Creilson, SAIC, NASA Langley Research Center; Michelle Wayland, U.S. Environmental Protection Agency

In April 2001, a large dust storm formed over the Gobi desert in northern China. Remote sensing satellite data and analyses of meteorological conditions were used in this study to follow the dust cloud from China, over the Pacific Ocean, and then coast to coast across the United States over a period of several weeks. Chemical speciation data from urban and rural particulate matter monitors were "matched" to the profile of Asian dust, and peak concentrations were plotted to show the progression of elevated concentrations due to Asian dust across the contiguous United States. Meteorological analyses, including backward and forward trajectories, were used to link the dust cloud overhead to the concentrations below. Also, the contribution of Asian dust to the total mass concentrations measured at the monitors was examined with respect to EPA's health standards for particulate matter.

DEVELOPMENT OF AN ETD PREAUDIT TECHNICAL CHECKLIST FOR AUDITS OF EPA RESEARCH STUDIES

Thomas J. Hughes, National Health and Environmental Effects Research Laboratory (NHEERL), ORD, U.S. EPA, Experimental Toxicology Division

An ETD Surveillance Checklist was developed last year, and it was presented at the 2002 EPA Annual QA Meeting in Phoenix, AZ. The Surveillance Checklist was necessary because QA review (i.e., a technical system review or TSR) is required of high visibility QA Category 1 and 2 research studies, and basic or exploratory research (QA 3 and 4 studies) are reviewed only as time permits. A TSR for the QA Manager, from initiation of the agenda to the delivery of the final report, can take several weeks of time to complete. It is virtually impossible to conduct a TSR on the majority of studies; reviews of ten percent of research studies in any year is the goal. To overcome this obvious obstacle to timely QA review of research projects, the ETD Surveillance Checklist was developed and utilized by the ETD QA Manager to evaluate and review major components of all research studies within ETD. The ETD Surveillance Checklist is a condensation of the 20-page technical systems review (TSR) checklist, is in a yes/no format, and covers notebooks, OPs, IRPs, computer files and data, data storage and filing, primary balance, primary pH meter, and two major pieces of equipment. The three-page ETD Surveillance Checklist concludes with a section on exemplary findings, areas for improvement, and corrective actions (if necessary), and is written by the QA Manager. The ETD Surveillance Checklist allowed the QA Manager to quickly (one hour) and efficiently evaluate the QA status of studies for each PI in the Division. Although obviously not as thorough as a TSR, it does provide yearly documentation to identify and correct deficiencies of all research studies within the Division, regardless of QA Category. The ETD Surveillance Checklist was written from the perspective of the auditor, and had limited use for the research scientist in the laboratory who needed to know exactly how to prepare for an audit or TSR. Consequently, an ETD Preaudit Technical Checklist was developed for the laboratory scientist, so they would be fully prepared for either an internal or external audit. The four-page Preaudit Technical Checklist is much more specific on how to prepare notebooks, data and computer files, and records and study files, than is the Surveillance Checklist. In the Preaudit Technical Checklist, emphasis is placed on the research protocol and operating procedures to insure that the laboratory has current protocols with the appropriate signatures. Quality control (QC) procedures are outlined. Animal procedures, sample identity, and chain-of-custody procedures are throughly reviewed. The Preaudit Technical Checklist highlights areas in the laboratory where previous audits have detected deficiencies. The Preaudit Technical Checklist has sections for comments and QA assistance needed by the laboratory, and is written by the laboratory scientist. The ETD Preaudit Checklist can be modified for major studies, and can be made more specific for interlaboratoty studies. It will be utilized in the 4-Lab Study that will start in ORD in October 2003, where 19 Principal Investigators in three EPA megalabs (NHEERL, NERL and NRMRL) and NCEA will be studying the toxicological effects of disinfectant by-products from chlorination and ozonation of drinking water. As the Program PI for the 4-Lab Study, Dr. Jane Ellen Simmons, told Tom Hughes, the 4- Lab Program QA Manager, "I don't want the lab scientists being blind-sided by an audit. The lab scientists should be fully informed of what will be inspected during any audit conducted during this 4-Lab Study." The ETD Preaudit Checklist is a guarantee that

the laboratory scientist will shine during either an internal or external audit. Both checklists are available from the author at Hughes.Thomas@EPA.Gov. This is an abstract for presentation which has been reviewed by the U.S. EPA; views expressed do not necessarily represent EPA policy.

ETD Preaudit Checklist **Page 1 of 4**

Experimental Toxicology Division, NHEERL, ORD, U.S. EPA, RTP, NC 27709
Thomas J. Hughes, ETD QA Manager (919-541-7644)

Principal Investigator: ____
Branch Chief:____
Audit Type:____
Date:_________________ Location: ______________________________
Reviewers:____
____

IRPs: INTRAMURAL RESEARCH PROTOCOLS

___ Is the IRP current (has it been reviewed by the PI within the last year, and is it signed and dated by the PI, Branch Chief and QA Manager)?

___ Has the IRP ***been revised*** within the last five years (umbrella IRPs) ? More realistically, ***IRPs should be revised*** every two years, or whenever the methods or personnel change significantly. IRPs can always be amended if changes are minor (e.g., addition of new student).

___ Do all personnel have a copy of the IRP?

___ Is a copy of the IRP in the lab, available to everyone who is conducting experiments?

Comments:____
____

OPs: OPERATING PROCEDURES

___ Are OPs current (signed and updated during the last two years)?

___ Are OPs present in the lab?

___ Is a complete copy of the OPs in a central file in the PIs office?

___ Do OPs need to be written for new procedures?

___ Is there an inventory attached to the OPs?

___ Is the OP inventory current?

Comments:____
____

NOTEBOOKS:

___ Are there labels on the notebook cover written with indelible ink or paint?

___ If the notebooks are looseleaf, is there a header on each page uniquely identifying the project (code), date and page number (can use rubber stamp)?

___ Is the name of the scientist on the cover?

NOTEBOOKS: continued

___ Is the project name and code on the cover (e.g., WTC-2002)?
___ Are inclusive dates on the cover?
___ Are the signatures of all scientists and initials on the inside cover?
___ Is the Table of Contents completed?
___ Is black ink used for all entries (**never** use pencil or white-out) ?
___ Are all pages dated and initialed by the scientist?
___ Has the PI reviewed notebook data and initialed and dated each page?
___ Are headers for sections present (Purpose and Conclusions , at a minimum)?
___ Does each scientist have their own notebook?
___ Are notebooks sequentially numbered at the end of the project (Notebook 1 of 4, etc)?
___ Are projects placed in separate notebooks (very important)? Try not to have notebooks with multiple scientists in it - sometimes unavoidable.

Comments:____
____

QC: QUALITY CONTROL

___ Are positive and solvent controls present for each experiment?
___ Are acceptance/rejection criteria documented?
___ Are results replicated?
___ Are equipment QC samples run before and after the samples are tested?
___ Are QC samples within expiration dates (e.g., pH buffers especially)
___ Are weights for balances stainless steel, Class1?
___ Are QC samples conducted with each experiment (e.g., spikes for GCs)?
___ Are instrument calibration procedures documented?
___ Are inspection and acceptance procedures for consumables and supplies documented?
___ Did a statistician review the IRP and data, especially for QA 1,2 studies?

Comments:____
____

EQUIPMENT:

___ Was the equipment (balance, pH meter, GC/MS) calibrated by an outside Agent during the last year?
___ Is this inspection documented on the equipment?
___ Is there a maintenance agreement on the equipment?
___ Is there a logbook for the equipment?

EQUIPMENT: continued

___ Are OPs near the equipment?
___ Are calibration procedures (OPs/manual) for the equipment nearby?
___ Are controls tested and documented *both before and after* the samples are tested?

Comments:____
____

ANIMALS:

___ Is the LAPR Current?
___ Is a reliable method of identifying the animals during the experiments used?
___ Is this method of identification documented in the IRP?
___ How are sick animals identified?
___ How are sick animals reported to the PI?
___ Are animals tested for disease?
___ Is animal food and water tested and are results documented?
___ Who handles the animals in the laboratory?
___ Are they properly trained?
___ Is the training of the personnel who handle the animals current?
___ Is this training documented?

Comments:____
____

SAMPLES:

___ Are samples uniquely identified (labels work best, especially for samples that will be stored for a long time)?
___ Samples can be identified by study code-year-number (e.g., WTC-2002-001)
___ Are samples properly stored?
___ Are sampling handling procedures documented?
___ Will chemical analyses of the samples be conducted (important for QA 1,2 studies)?
___ Was an expiration date determined for the samples?
___ Was a receipt date and an expiration date documented for the sample?
___ When samples were destroyed, was this documented in the study notebook?
___ When samples were delivered or transferred, was a chain-of-custody form signed and dated, and is this in the study file?

Comments:____
____

COMPUTER FILES:

___ Are computer software packages validated before use?
___ Are computer model numbers and software package numbers documented?
___ Does a coded inventory of all computer study files exist?
___ How are computer files backed up?
___ How often are computer files backed- up?
___ Where are back-up files kept (should not be in same place as primary data)?
__ How are computer data verified?
___ Who verifies data?
___ How often are data verified ?

Comments:____
____

STUDY FILE and MASTER FILE:

___ Does PI have all notebooks from study?
___ Does PI have all raw data from the study?
___ Does PI have copies of all computer files from study?
___ Does PI have all copies of all chain-of-custody forms from study?
___ Does PI have a sample inventory from study?
___ Does PI have any other study records in their possession (slides, pathology reports, etc.)?
___ Does PI have copies of all abstracts from study?
___ Does PI have copies of all reports and manuscripts from the study?
___ Does PI have all correspondence from the study?
___ Are all these documents inventoried (**master file**) and in the possession of the PI? The study file must be kept in the possession of the PI for five years after the publication of the data. The study file can then be archived with an SF-135 form (Detra Nance, 919-541-4239).

Comments:____
____

QA ASSISTANCE NEEDED BY LABORATORY

____
____

WRITTEN BY:______________________________ **DATE:**________________

PLACED IN STUDY FILE BY: ________________ **DATE:**________________

Quality Assurance Audits - Positive Outcomes

Joseph LiVolsi, U.S. EPA

The term "Quality Assurance" rarely brings about a warm-fuzzy feeling. Add "audit" (or the gentler term we now use - "assessment") to this, and you may see people searching desperately for a place to hide. But here's the irony. The tables have turned. You're the regional QA office, and Headquarters is coming to audit "you." There IS no place to hide! And you're faced with the following challenges (that you've so warmly offered as advice to those you've audited yourself) - welcoming the opportunity to showcase the systems you've so diligently developed and set in motion, remaining open to the possibility that some changes may actually be beneficial, fostering creative solutions to address any audit "findings" (another delicate term!), and cultivating cooperative means to implement positive changes to support the organization as a whole. Yes! Throwing down the pompoms and joining your own game! Turning the experience into a positive outcome!

The (New England) regional QA office was faced with such a challenge. Toward the end of FY01, an assessment from Headquarters identified deficiencies in the way the region was implementing quality assurance requirements for organizations receiving EPA financial assistance (or grant recipients). The system in place did not adequately ensure that these grant recipients conformed to the national QA requirements as stated in the American National Standard ANSI/ASQC E4-1994, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs. A task force was formed to address the audit findings and develop a strategy to implement the necessary corrective actions. Due to the nature of the deficiencies and the logistics essential to actualize the required changes, the task force was comprised of individuals from throughout the regional organization - including representatives from various Program Offices, Grants Specialists, Project Officers, as well as members of the Quality Assurance Unit. The task force, with support from upper management, joined together to develop and rollout a 4-hour "Quality Assurance Awareness Training" program. This training was mandatory for all regional Project Officers, Grant Specialist, and Quality Assurance Unit staff during FY02.

The training served to provide the audience with a clear understanding of the agency's national quality assurance requirements, the manner in which the region is to be implementing these requirements, and the roles and responsibilities of the regional staff in fostering adequate quality assurance implementation among the various grant recipients. In addition, the trainees participated in an interactive breakout session designed to build their confidence in understanding the quality assurance requirements (especially as related to the need, or not, for a Quality Assurance Project Plan) for some example projects currently underway within the region. By conveying a strong team approach in both the delivery and content of the training, the message came out loud and clear - we all have a shared responsibility in the implementation of adequate quality assurance measures across the agency. A followup assessment, performed by the regional QA staff a year later, demonstrated that the region is well underway in experiencing a positive outcome to a focused quality assurance audit.

Planning Environmental Data Collection Programs: Perspectives From Nigeria

Ibrahim Salau, Environmental Resources Managers Limited

Environmental data is the bedrock of various decisions resulting from several environmental programs. Such data collection efforts may range in scale from simple to extensive depending on the objectives of the program involved. In most cases, significant amount of resources are inherently involved. The collection of environmental data is now fairly standardized with the establishment of systematic procedures like the EPA Quality process for environmental programs. Specifically, the EPA system recommends the Data Quality Objective (DQO) process as a basis for the planning of environmental data collection programs. The DQO is a graded scientific approach to environmental data collection planning. However, systematic approaches to environmental data collection programs like the DQO is yet to enjoy wide acceptance in developing countries like Nigeria. This paper is a cogent comparative review of the existing regulatory framework for planning environmental data collection programs in Nigeria and the EPA DQO process. It illustrates the major impediments to the adoption of a systematic approach to data collection programs in Nigeria with two key case studies. It presents key lessons and potentials for the integration of systematic approaches to environmental data collection programs in Nigeria. It concludes with succinct recommendations on how identified gaps could be bridged to ensure the generation of sound environmental data in Nigerian thereby fostering sound sustainable development decision making.

Developing and Implementing Universal Standards for 'Quality Electronic Records Practices' and the State-of-the-Art of Electronic Lab Notebooks

Rich Lysakowski, the Collaborative Electronic Notebook Systems Association
and the Global Electronic Records Association

The Global Electronic Records Association (GERA) is proactive problem-solving partnership and international association for people dealing with electronic records in government and industry. GERA's mission is to overcome the Grand Challenge of securing electronic evidence for long-term preservation and access. GERA includes many corporations,

US EPA, PTO, FDA, NARA, many US state archives, and their equivalents worldwide. GERA's fast-track development efforts are creating and implementing comprehensive standards for "Quality Electronic Records Practices" (QERPs).

The research and standards creation work is jointly funded by industry via CENSA, the Collaborative Electronic Notebook Systems Association, and by

the National Historical Publications and Records Commission, the arm of the US National Archives and Records Administration that funds research.

The Quality Electronic Records Practices are government and industry standards that cover electronic records organizational programs and technology system reference models. The full set of QERPs include specifications and guides for requirements, policies, procedures, validation, auditing, certification, and training on permanent electronic records and archives management systems. The QERPs focus on high-value,

high-consequence records that are retained long-term to protect intellectual property (trade secrets, patents, etc.), to show regulatory

compliance, for use as evidence any civil or criminal litigation, or to show historical accuracy. Helping organizations implement compliance with 21 CFR Part 11, EPA's CROMERRR, and other eRecords regulations are explicit objectives of the QERPs.

The QERPs synthesize the best models, specifications, standards, regulations, practices, and research results from government, academic, and industrial organizations globally. The QERPs are a comprehensive knowledge framework that unify and extend these sources to cover the entire lifespan of permanent electronic records, even as their underlying technologies and program components change. The framework includes detailed engineering-style specifications as well as guidelines understandable by lay people and practitioners. Leading electronic records experts from industry and government are being used to author, review, test, and implement the QERPs in real environments.

This talk will review the goals of the QERPs, and practical experience to test and implement them. It will also cover the work of CENSA to catalyze the state of the art in Collaborative Electronic Notebook Systems, component-based software technologies,

and data integration products and standards. The EPA and other government agencies concerned with replacing paper-based notebooks

and recordkeeping systems with electronic equivalents will benefit from automated Electronic Laboratory Notebooks because they greatly exceed the capabilities of paper-based systems and offer immeasurable benefits for collaboration.

Measurable Product Features for Information

Jeffrey Worthington, OEI Director of Quality

The Office of Environmental Information will present a model for information quality which provides for the identification of measurable product features for information in both production and distribution operations. The listing of the product features will allow EPA quality managers to incorporate measurement of these product features into current measurement and reporting systems. Examples will be given that are applicable to program, research, Web, and regulatory operations.

W.E. Deming and the Red Bead Experiment

Jeffrey Worthington, OEI Director of Quality

SESSION DESCRIPTION: The Office of Environmental Information presents the classic Red Bead Experiment which considers the basic processes in a production operation. This is an interactive training session that is very similar to the experiment offered by Deming to senior management in the US and Japan. A review of basic statistical approaches to evaluate process output is offered. Audience participation is required of some and encouraged for all. The session activitities include a summary of W.E. Deming quality approach and interactive activities. During the experiment, audience members will be invited to share observations, make their own records of the activity, and participate in the simple statistical analysis of the company process.

Conducting Internal QMS Audits

Gary L. Johnson, U.S. EPA, Quality Staff

This workshop describes internal audit techniques and applications, particularly for Federal and State environmental organizations and for environmental analytical laboratories. Key differences from traditional external auditing is emphasized. Concepts of value-added auditing and process auditing will be introduced and discussed within the context of internal audit programs.

INTRODUCTION

Audits are an important tool to aid managers in determining the suitability of products, the effectiveness of operations and services, and conformity with criteria and objectives. Typically, three types of audits are typically applied to quality management systems (QMS): internal (or first party), supplier (or second party), and external (or third party). The U.S. Environmental Protection Agency (EPA) has conducted external audits of the QMS in various Agency organizations for more than 20 years in order to assure their conformity with EPA policies and requirements for quality. While these external audits provide important information to management, their value to the audited organization may have been limited in terms of determining if the organization's operations and services are as effective as expected. In such cases, the organization may find more value in developing and applying a program of internal audits. This technical session will provide:

- a better understanding of the value of internal audits and how they differ from other audit types;
- a discussion of the principles of internal audits;
- guidance on managing effective internal audit programs;
- discussion of a model for internal audits in an EPA or other government facility; and
- guidance on selecting, developing, and evaluating internal auditors.

INTERNAL AND EXTERNAL AUDITS

In the most simplistic sense, *internal audits* are audits conducted by an organization on itself and *external audits* are audits conducted on the organization by someone from outside the organization. In reality, however, boundaries between internal and external audits may vary depending upon the complexity of the organization. For example, are audits conducted by EPA's Quality Staff on a Region internal since the Quality Staff is also part of EPA? Or, is that an external audit since the Quality Staff is independent of the Region being audited?

In this case, we are considering audits of quality management systems (QMS); therefore, we may define internal audits as those conducted by auditors who are a part of the organization "owning" the QMS. In the above example, internal audits in an EPA Region would be conducted by Regional personnel, not by the EPA Headquarters Quality Staff.

Most management systems standards require audits to be performed. ISO 9001:2000 is, perhaps the most widely used QMS standard in today and requires that internal quality audits examine the quality system for conformity to the standard. EPA uses ANSI/ASQC E4:1994 as the basis for its QMS requirements. E4 is presently undergoing the mandatory re-authorization process by the American National Standards Institute (ANSI), which will be completed later this year. The 2003 edition of E4 is recognized by the Registrar Accreditation Board (RAB) as an equivalent standard to ISO 9001:2000 for the purposes of auditor certification and recognition. This will apply external and internal auditors.

PRINCIPLES OF INTERNAL AUDITS

ISO 19011, the new International Standard for auditing QMS and environmental management systems (EMS), provides several basic principles for auditing in general. For auditors, it is expected that they:

- exhibit ethical conduct,
- assure fair presentation,
- apply due professional care,
- be impartial and objective, and
- use an evidence-based approach.

These also apply to internal audits. Perhaps the most important principle is that ***internal auditors should be independent of the activities they audit***.

ISO 9000:2000 defines an audit as a “systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.” This definition is applicable to all types of audits.

MANAGING INTERNAL AUDIT PROGRAMS

An internal audit program, like any audit program, should have specific objectives and should have its extent fully defined. For example, organizations having quality systems based on ISO 9001:2000 are required to have internal audit programs as a criterion for certification. Other internal audit programs may be established to verify that laboratory processes are operating within control limits. For EPA organizations, internal audits provide an excellent means of assuring that the organization’s quality system is conforming to its Quality Management Plan (QMP).

The responsibility for managing an internal audit program should be assigned to one or more persons having a good general knowledge of audit principles and practices, and having a good understanding of the objectives of the audit program. Most important, perhaps, the audit program manager should have a good understanding of the competencies needed for the program’s auditors. (Such competencies will be discussed later in more detail.) The audit program manager will be responsible for planning and scheduling the internal audits, selecting the auditors, maintaining appropriate records, monitoring the performance and effectiveness of the audit program, and reporting to top management on the overall achievements of the program.

CONDUCTING INTERNAL AUDITS

Conducting audit activities consists of the following general steps:

- initiating the audit,
- conducting document reviews,
- preparing for the audit activities,
- conducting the audit activities,
- preparing and distributing the audit report,
- completing the audit, and
- conducting audit follow-up, if appropriate.

These steps, with some variation, apply to internal audit programs. Typically, internal audits are not applied to the same degree or level as external audits. Internal audits are usually less formal, but may not be less intensive than external audits, depending upon the objectives of the audit program.

Initiating the Audit

Initiating and planning an internal audit begins with the appointment of an audit team leader. In some cases, an internal audit program may have only one auditor and involve only one audit. This is typically the case for small organizations. Even so, the single auditor may not audit his/her own work. Where an audit team is appropriate, the competence of the auditors needed should be the principal consideration along with the knowledge and skills needed to satisfy the objectives of the audit. For many internal audits, the auditors are selected from the rank and file members of the organization and may be managers, technical staff, or clerical staff. For example, an internal audit of an analytical laboratory should include auditors generally knowledgeable in the analytical processes to be audited.

Conducting Document Reviews

Planning the audit should include the review of relevant documents and records, such as a QMP, standard methods and operating procedures, QA Project Plans, and other planning documentation. These documents provide the necessary baseline for the audit criteria and usually provide some early indications of conformity.

Preparing for the Audit Activities

The audit team leader should prepare an audit plan to provide the basis for agreement regarding the conduct of the audit. This is a recommended practice even for internal audits so that all parties understand and agree to the activities to be audited, who may be interviewed, what evidence may be gathered, and how the results of the audit will be used. This will foster a “no surprises” approach and will help to relieve the normal tension associated with auditing in general. In the case of internal audits, the audit plan does not need to be a formal document or be exceptionally detailed, but it should explicitly define the criteria for the audit.

The audit team leader should also assign specific work to the audit team, based on the audit plan. The assignments should take into account the competence of each auditor, the need for independence, personal attributes, and the effective use of resources. After assignments are made, each audit team member should prepare any work documents that may be needed for recording audit information, including checklists and forms.

Conducting the Audit Activities

Audits typically begin with the opening meeting in order to brief the auditee's management on the conduct of the audit. In the case of internal audits, the auditee is also the customer of the audit and will already be informed of the objectives, but an internal audit may involve middle and first-level managers who may not be familiar with the audit objectives. An opening meeting does not need to be a formal affair, but should focus on describing the audit plan, reviewing the audit schedule, and allowing the opportunity for the auditee to ask questions.

Information collected during the audit should be verified whether obtained through interviews or file reviews. Only information that is verifiable may be audit evidence. When evaluating audit evidence against the audit criteria, it is often helpful to ask, "So what?" The "so-what" test may help to put possible audit findings into perspective relative to the audit objectives. In the case of internal audits, it may be appropriate for the auditors to offer suggestions or recommendations based on the audit findings determined. After all, the internal auditor is a part of the same organization. At the conclusion of information gathering, the audit team should review the audit findings, evidence, and any other information against the audit objectives and agree on preliminary audit conclusions. Such conclusions will identify any non-conformities and may produce specific corrective action requests (CARs).

Internal audits do not always require a formal closing meetings as typically found in other types of audit programs. It may suffice only to communicate the results to management informally.

Preparing and Distributing the Audit Report

Depending upon the objectives of the internal audit program, an audit report may be necessary to document the results of the audit. This report should be prepared and issued within an agreed time frame, and should be distributed to those identified in the audit plan.

Completing the Audit

The audit is complete when all activities described in the audit plan have been completed and the audit report has been distributed.

Conducting Audit Follow-up

For most audits, the audit is complete when the audit report is distributed. However, some external audits may include provisions for audit follow-up in the audit plan. For internal audits, though, the auditee is also the customer for the audit and audit follow-up is frequently expected and included. The resolution of corrective action requests (CARs) often involves using the same internal auditors to verify implementation of the CARs and validate their effectiveness.

SELECTING, DEVELOPING, AND EVALUATING INTERNAL AUDITORS

The confidence and reliance on any audit program depends on the competence of the auditors conducting the audits. For most organizations, competent internal auditors may be developed from the existing staff, but, for others (and particularly small organizations), it may be necessary to obtain the services of external auditors in order to carry out the internal audit program. Competence is based on demonstrated personal attributes and knowledge and skills gained through education, work experience, and auditing experience. Personal attributes include being ethical, open-minded, observant, perceptive, and self-reliant, and are applicable to all auditors. Internal auditors, because the typically come from other jobs in the organization, should be "willing" to accept the new role of auditor and the new responsibilities with that role.

Internal auditors may not need extensive technical backgrounds or audit experience. Auditing techniques, such as interviewing skills can be taught to novice auditors and hands-on training may be provided through mentoring by experienced auditors. Familiarization with the quality system is key and special training may by necessary to cover its full scope.

Because internal auditors "come from the ranks," there may be some tension created by their new role and some resistance by auditees to cooperate fully with a former peer. It is management's responsibility to assure that the auditor's responsibility is defined and communicated to all staff so that the auditor will be able to function effectively. In like manner, the auditor must remain objective and diplomatic at all times.

After the internal has been completed, the audit team leader and the audit program manager should evaluate the performance of the auditors and provide relevant feedback to enable them to improve their auditing skills. This ensures the continued relevance and effectiveness of the internal audit program and a supply of competent auditors.

SUMMARY

Internal audit programs differ from external audit programs even though they both share many of the same audit principles. These differences make internal audits generally easier to plan and conduct, but also make the selection of competent auditors more difficult. Understanding the differences can make internal audit programs more effective for an organization.

Internal audit programs provide organizations with opportunities for assessing the conformity and effectiveness of their quality systems and processes and at times needed by the organization. Such programs may be particularly beneficial in assuring that an organization is adequately prepared for an external audit by a third party. Other benefits can include lowering costs and expenses, finding and correcting problems, and identifying improvements.

REFERENCES

I. Block, Marilyn R., and I. Robert Marash, *Integrating ISO 14001 into a Quality Management System*, Second Edition, ASQ Quality Press, Milwaukee, WI (2002).

II. ANSI/ASQC E4:1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, American Society for Quality, Milwaukee, WI (January 1995).

III. Pronovost, Denis, *Internal Quality Auditing*, ASQ Quality Press, Milwaukee, WI (2000).

IV. ISO 19011:2002, *Guidelines on Quality and/or Environmental Management Systems Auditing*, International Organization for Standardization, Geneva, Switzerland (October 2002).

V. Russell, J.P. (Ed.), *The Quality Audit Handbook*, 2nd Edition, ASQ Quality Audit Division, ASQ Quality Press, Milwaukee, WI (2000).

VI. Phillips, Ann W., *ISO 9001:2000 Internal Audits Made Easy*, Quality Techniques, Huntsville, AL (2002).

Environmental Decisions using Data Expressed with the Measurement Uncertainty

Marlene Moore, Advanced Systems, Inc.

The presentation demonstrates the use of the expression of measurement uncertainty in making environmental decisions. Data generated as part of a quality program includes routine quality control and quality assurance practices and is produced within the framework of a quality system as defined in the ANSI/ASQC E-4 standard for data collection activities. The expression of the results with the measurement uncertainty provides the final data user with a uniform method of comparison of the data quality and allows the decision maker to understand the variability of the data presented.

All measurement operations must use quality assurance statements so the structure of the variance in the data is defined and known. Every aspect of compliance monitoring and site investigations and remediation activities must know the sources of the variations in the data in order to minimize the effect on the data used for decision making. The demonstration of an understanding and knowledge of the measurement process ensures the generation of defensible data.

The international definition for the expression of measurement uncertainty has been defined in the "Guidelines for Expression of Measurement Uncertainty" (GUM). This uniform definition requires the reevaluation of the uncertainty expressions being used when expressing measurement results. The use of a consistent definition for expressing uncertainty allows the data to be presented with the measurement value and the related plus or minus value. The plus or minus value expresses the range of values within which the reported value can be said to lie within a specified level of confidence. This range of values allows the decision maker to compare the range to the decision level for that project or regulatory program. When the range of values overlaps the decision level the decision is not as straight forward as a decision where the range of values is above or below the decision level. It is noted that the traditional forms of data quality indicators, data validation qualifier codes and other currently practiced data attributes (e.g.: bias, precision, repeatability, reproducibility) are all incorporated into the international definition for the expression of uncertainty.

The presentation demonstrates the use of the international definition for expressing measurement uncertainty and using this reporting method for making environmental compliance and site investigations or clean-up decisions. The presentation combines the tools from various federal and international sources in order to make sound scientific environmental decisions. The tools discussed during the presentation include: the EPA approach defined in the R and G series of documents, Dept of Navy Uncertainty Calculator for expression of uncertainty of the total variability of data collection and the use of Visual Sample Plan for expressing data in statistical terms. This presentation assumes that the sampling and testing plan, implementation and validation incorporate a mature quality system approach to minimize or eliminate mistakes.

References:

National Environmental Laboratory Accreditation Conference (NELAC) Standard, approved May 2001 and July 2002, US EPA

"Environmental Analytical Uncertainty Estimation: Nested Hierarchical Approach", William Ingersoll, Charleston, S.C, 2000

"Estimation of Laboratory Analytical Uncertainty Using Laboratory Control Samples", Thomas Georgian, U.S. Army Corps of Engineers, "Environmental Testing & Analysis", Nov/Dec, 2000 pp 20-24, 51

"Guide to the Expression of Uncertainty in Measurement", ISO, Geneva, Switzerland 1993 (ISBN 92-67-10188-9) Known as "GUM"

"International Vocabulary of Basic and General Terms in Metrology", VIM ISO (1993), second ed, International Organization for Standardization, Geneva, Switzerland, ISBN 92-67-01075-1

"Quantifying Uncertainty in Analytical Measurement" EURACHEM/CITAC Guide, Second Edition: 2000 (Eurachem)

"Quality Assurance of Chemical Measurements ", John Keenan Taylor, Lewis Publishers, 1987

"The Expression of Uncertainty and Confidence in Measurement", M3003, United Kingdom Accreditation Service (UKAS), England, edition 1, December 1997

How to Incorporate Information Quality Considerations into Your Existing Quality Management Plan

Jeffrey Worthington, OEI Director of Quality; Nancy Wentworth, Quality Staff Director

EPA organizations are now placing an increased emphasis on the quality of information that is maintained by the organization as a strategic resource. Continuing to manage, monitor, and ensure the quality of the production and distribution of the organization's information may be of equal importance to ensuring that scientific measurements are of adequate quality to support a decision. The Office of Environmental Information (and the Quality Staff) will present methodology for revising an organization's Quality Management Plan to strengthen procedures to ensure the quality of information production and distribution operations as part of the quality system. Attendees to this session may be able to use the information to improve their quality system.